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Patent #3

Attorney Docket: 259/061

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Anna P. Catania, et al.

Serial No.: 10/015,055

Filed: December 10, 2001

For: A COMPOUND AND METHOD
FOR THE TREATMENT OF
SINUSITIS

Group Art Unit: 1646

Examiner: not yet assigned

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TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

I. DOCUMENTS ENCLOSED:

Applicant submits the following documents with this Transmittal Letter.

- (1) Information Disclosure Statement;
- (2) Form PTO-1449;
- (3) References AA- EF.

LA-229880.1

CERTIFICATE OF MAILING
(37 C.F.R. §1.8a)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.

March 8, 2002
Date of Deposit

Rachel Marquez
Name of Person Mailing Paper

Signature of Person Mailing Paper

II. REQUEST FOR EXTENSION OF TIME:

The proceedings herein are for a patent application and the provisions of 37 CFR § 1.136 apply.

- ☐ Applicant(s) petitions for an extension of time under 37 CFR § 1.136 [fees: 37 CFR § 1.17(a)(1)-(5)] for the total number of months checked below:

EXTENSION (months)	FEE FOR SMALL ENTITY	FEE FOR OTHER THAN SMALL ENTITY
<input type="checkbox"/> one month	\$55.00	\$110.00
<input type="checkbox"/> two months	\$195.00	\$390.00
<input type="checkbox"/> three months	\$445.00	\$890.00
<input type="checkbox"/> four months	\$695.00	\$1,390.00
<input type="checkbox"/> five months	\$945.00	\$1,890.00

Fee

- ☒ If any extension fee is required, please consider this a petition therefor.

III. FILING FEES

- ☒ Applicant claims small entity status pursuant to 37 CFR 1.27.

BASIC FILING FEE:					\$0.00
Total Claims	0	-	20	= 0 x \$18.00	\$0.00
Independent Claims		-	3	= 0 x \$80.00	\$0.00
Multiple Dependent Claims	\$270	(if applicable)		<input type="checkbox"/>	\$0.00
Surcharge 37 CFR § 1.16(e)	\$130	(if applicable)		<input type="checkbox"/>	\$0.00
TOTAL OF ABOVE CALCULATIONS					\$0.00
Reduction by ½ for Filing by Small Entity. Note 37 CFR §§ 1.9, 1.27, 1.28.					\$0.00
Extension of Time (from above)					\$0.00
Assignment -- \$40 (if applicable)					\$0.00
TOTAL FEES SUBMITTED HEREWITH					\$0.00

IV. METHOD OF PAYMENT OF FEES:

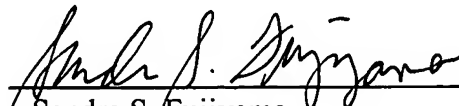
- ☐ A check in the amount of \$_____ is enclosed to cover the fee for filing of Supplemental Disclosure Statement.
- ☐ Charge Lyon & Lyon's Deposit Account No. 12-2475 in the amount of \$_____.

☒ The Commissioner is authorized to charge Lyon & Lyon's Deposit Account No. 12-2475 for any fees required under 37 CFR §§ 1.16, 1.17 and 1.445 that are not covered, in whole or in part, by a check enclosed herewith and to credit any overpayments to said Deposit Account No. 12-2475.

Respectfully submitted,

LYON & LYON LLP

Dated: 3/8/02

By: 
Sandra S. Fujiyama
Reg. No. 46,713



22249

PATENT TRADEMARK OFFICE

LYON & LYON LLP
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633 W. Fifth Street
Los Angeles, CA 90071
(213) 489-1600

FORM PTO-1449 LIST OF PATENTS AND OTHER ITEMS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%;">ATTY. Docket NO. 259/061US</td> <td style="width:50%;">SERIAL NO. 10/015,055</td> </tr> <tr> <td colspan="2">APPLICANT: Anna P. Catania, et al.</td> </tr> <tr> <td>FILING DATE: 12/10/01</td> <td>GROUP: 1646</td> </tr> </table>	ATTY. Docket NO. 259/061US	SERIAL NO. 10/015,055	APPLICANT: Anna P. Catania, et al.		FILING DATE: 12/10/01	GROUP: 1646
ATTY. Docket NO. 259/061US	SERIAL NO. 10/015,055						
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U.S. PATENT DOCUMENTS							
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE	
AA	09/533,341		Catania Anna P. et al.			3/23/00	
AB	5,028,592	7/02/91	Lipton, J.M.,			8/5/88	
AC	5,157,023	10/20/92	Lipton, J.M.,			3/21/91	
AD	09/535,066		Lipton, J.M.,			3/23/00	
AE	60/200,287		Lipton, J.M.,			4/28/00	
AF	09/774,282		Lipton, J.M.,			1/29/01	
AG	5,739,111	4/14/98	Mahe, Yann			4/29/96	
AH	6,001,812	12/14/99	Mahe, Yann			1/23/98	

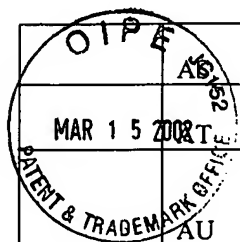
FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES NO	
AI	PCT/US00/07846	3/23/00	WIPO				
AJ	WO/97/10838	3/27/97	WIPO				
AK	WO/99/58101	11/18/99	WIPO				
AL	EP 0972 522 A1	1/19/00	EPO				
AM	2,784,028	4/7/00	France				
AN	WO00/42856	7/27/00	WIPO				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)	
AO	Airaghi, L., et. al., "Elevated concentrations of plasma α -MSH are associated with reduced disease progression in HIV-infected patients," J. Lab. Clin. Med. 133(3) 309-315 (1999).
AP	Airaghi L, Lettino M, Manfredi MG, Lipton JM, Catania A. Endogenous cytokine antagonists during myocardial ischemia and thrombolytic therapy. Am. Heart J. 130: 204-211, 1995.
AQ	Airaghi L. Garofalo L. Cutuli MG. Delgado R. Carlin A. Demitri MT. Badalamenti S. Graziani G. Lipton JM. Catania A. Plasma concentrations of α -melanocyte-stimulating hormone are elevated in patients on chronic haemodialysis. Nephrology Dialysis Transplantation 15:1212-1216, 2000.
AR	Baker, M., et. al., "The Relationship between Interleukin-6 and Herpes Simplex Virus Type-1: Implications for Behavior and Immunopathology," Brain Behav. Immun. 13(3):201-11 (1999)

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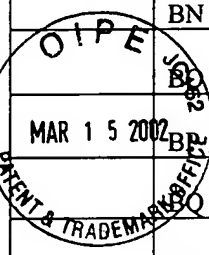
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	AS	Baker, et al., "Principles of Ambulatory Medicine," <i>Williams and Wilkins</i> (1982)
	AT	Barcellini, W., et. al., "Inhibitory Influences of α -MSH peptides on HIV-1 expression in Monocytic cells," 12 th World AIDS Conference Geneva, Abstract No. 60685, June 28-July 3, 1998.
	AU	Barcellini W, La Maestra L, Clerici G, Garofalo L, Brini AT, Lipton JM, Catania A. α -MSH peptides inhibit HIV-1 expression in chronically infected promonocytic U1 cells and in acutely infected monocytes. <i>Journal of Leukocyte Biology</i> 68:693-699, 2000.
	AV	Bhattacharya A., et. al., "Effect of Cyclic AMP on RNA and Protein Synthesis in <i>Candida albicans</i> ," <i>Biochem, Biophys. Res. Commun.</i> , 77: 1438-44 (1977)
	AW	Bickers, D., Sun-Induced Disorders, <i>Emergency Medicine Clinics of North America</i> , 3(4): 659-663, 660 (1985).
	AX	Capsoni, F., et. al., "Effect of Corticosteroids on Neutrophil Function: Inhibition of Antibody-dependent Cell-Mediated Cytotoxicity (ADCC)," <i>J. Immunopharmacol.</i> 5, 217-30 (1983)
	AY	Cartledge, J.D., et. al., "Clinically Significant Azole Cross-Resistance in <i>Candida</i> Isolates from HIV-Positive Patients with Oral Candidosis," <i>AIDS</i> 11:1839-44 (1997).
	AZ	Catania, A., et. al., " α -Melanocyte Stimulating Hormone in the Modulation of Host Reactions," <i>Endocr. Rev.</i> 14, 564-576 (1993).
	BA	Catania, A., et. al., "Melanocortin Peptides Inhibit Production of Proinflammatory Cytokines in Blood of HIV-Infected Patients," <i>Peptides</i> , 19(6): 1099-1104 (1998)
	BB	Catania, A., et. al., "The Neuropeptide α -MSH in HIV Infection and Other Conditions in Humans," <i>Ann. N.Y. Acad. Sci.</i> 840: 848-856 (1998).
	BC	Catania, A.; et. al., "The Neuropeptide α -MSH has Specific Receptors on Neutrophils and Reduces Chemotaxis in Vitro," <i>Peptides</i> 17, 675-679 (1996).
	BD	Catania A, Airaghi L, Lipton JM. α -MSH in normal human physiology and disease states. <i>Trends Endocrinol. Metab.</i> 11:304-308, 2000.
	BE	Catania A, Delgado R, Airaghi L, Cutuli M, Garofalo L, Carlin A, Demitri MT, Lipton JM. α -MSH in systemic inflammation: central and peripheral actions. <i>Annals of the New York Academy of Sciences</i> , 885:183-187, 1999.
	BF	Catania A, Grazia M, Manfredi MG, Airaghi L, Ceriani G, Gandino A, Lipton JM. Cytokine antagonists in infectious and inflammatory disorders. <i>Annals of the New York Academy of Sciences</i> 741: 149-161, 1994.
	BG	Catania A, Lipton JM. α -melanocyte-stimulating hormone peptides in host responses: from basic evidence to human research. <i>Annals of the New York Academy of Sciences</i> 680: 412-423, 1993.
	BH	Catania A, Cutuli M, Garofalo L, Airaghi L, Valenza F, Lipton JM, Gattinoni L. Plasma concentrations and anti-L-cytokine effects of α -melanocyte stimulating hormone in septic patients. <i>Crit. Care Med.</i> 28: 1403-1407, 2000.
	BI	Catania A, Airaghi L, Motta P, Manfredi MG, Annoni G, Pettenati C, Brambilla F and Lipton JM. Cytokine antagonists in aged subjects and their relation with cellular immunity. <i>Journal of Gerontology: Biological Sciences</i> 52A: B93-97, 1997.
	BJ	Catania A, Manfredi MG, Airaghi L, Vivirito MC, Capetti A, Milazzo F, Lipton JM and Zanussi C. Plasma concentration of cytokine antagonists in patients with HIV infection. <i>Neuroimmunomodulation</i> 1: 42-49, 1994.
	BK	Catania A, Airaghi L, Manfredi MG, Vivirito MC, Milazzo F, Lipton JM, Zanussi C: Proopiomelanocortin-derived peptides and cytokines: relations in patients with acquired immunodeficiency syndrome. <i>Clinical Immunology and Immunopathology</i> 66: 73-79, 1993.
	BL	Cavello, J. and Deleo, V., Sunburn, <i>Dermatologic Clinics</i> , 4(2): 181-187, 181 (1986).
	BM	Ceriani, G., et. al., "Central Neurogenic Antiinflammatory Action of α -MSH: Modulation of Peripheral Inflammation Induced by Cytokines and other Mediators of Inflammation," <i>Neuroendocrinology</i> , 59:138-143 (1994)

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	APPLICANT: Anna P. Catania, et al.	
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	BN	Ceriani G, Diaz J, Murphree S, Catania A, Lipton JM. The neuropeptide alpha-melanocyte-stimulating hormone inhibits experimental arthritis in rats. <i>Neuroimmunomodulation</i> 1:28-32, 1994.
	BR	Chiao H, Foster S, Thomas R, Lipton J, and Star RA. α -MSH reduces endotoxin-induced liver inflammation. <i>J. Clin. Invest.</i> 97: 2038-2044, 1996.
	BR	Csata, M. et. al., "Enhancement of <i>Candida albicans</i> killing activity of separated human epidermal cells by alpha-melanocyte stimulating hormone," <i>British Journal of Dermatology</i> , 121(1) 145-147 (1989).
	BR	Cutuli, M. et. al., "Antimicrobial effects of α -MSH peptides," <i>Journal of Leukocyte Biology</i> 67:233-239 (2000).
	BR	Deeter, L.B., et. al., Antipyretic Properties of Centrally Administered α -MSH Fragments in the Rabbit, <i>Peptides</i> 9, 1285-1288 (1989).
	BS	Delgado, R., et. al., "Melanocortin peptides inhibit production of proinflammatory cytokines and nitric oxide by activated microglia," <i>Journal of Leukocyte Biology</i> , 63: 740-745 (1998)
	BT	Domk-Optiz, I., et. al., "Stimulation of Macrophages by Endotoxin Results in the Reactivation of a Persistent Herpes Simplex Virus Infection," <i>Scand J. Immunol.</i> 32(2):69-75 (1990)
	BU	Eberle, A. and Schwyzer, R., "Hormone-Receptor Interactions, <i>Clinical Endocrinology</i> 5, Suppl., 41s-48s (1976)
	BV	Eberle, A.N., <i>The Melanotrophins</i> , Karger, Basel, Switzerland (1988).
	BW	Fauci, A.S., "Host Factors in the Pathogenesis of HIV-induced Disease," <i>Nature</i> 384: 529 (1996)
	BX	Fitzpatrick, et al., Acute Effects of Ultraviolet Radiation on the Skin: The Sunburn Reaction, <i>Dermatology in General Medicine</i> , 4th Edition, 1651-1655, 1651 (1993).
	BY	Fitzpatrick, et al., "Color Atlas and Synopsis of Clinical Dermatology," (1983)
	BZ	Foster, J. Sunburn, <i>eMedicine - Online Medical Reference Textbook</i> , (last modified may 1, 2000), < http://emedicine.com/emerg/topic798.htm .
	CA	Fox, J. A., et.al., "Immunoreactive α -Melanocyte Stimulating Hormone, Its Distribution in the Gastrointestinal Tract of Intact and Hypophysectomized Rats," <i>Life. Sci.</i> 28, 2127-2132 (1981).
	CB	Galimberti D, Baron PL, Meda L, Prat E, Scarpini E, Delgado R, Catania A, Lipton JM, Scarlato G. α -MSH peptides inhibit production of nitric oxide and tumor necrosis factor- α by microglial cells activated with β -amyloid and interferon γ . <i>Biochemical Biophysical Research Communications</i> 263: 251-256,1999.
	CC	Getting, et al., POMC Gene-Derived Peptides Activate Melanocortin Type 3 Receptor on Murine Macrophages, Suppress Cytokine Release, and Inhibit Neutrophil Migration in Acute Experimental Inflammation, <i>J. Immunol.</i> , vol. 162, No. 12, pgs. 7446-7453 (1999)
	CD	Harris et al., Alpha-melanocyte stimulating hormone (α -MSH) and melanin-concentrating hormone (MCH) stimulate phagocytosis by head kidney leucocytes of rainbow trout (<i>Oncorhynchus mykiss</i>) in vitro, <i>Fish & Shell Immunol.</i> , Vol. 8, 8:631-638 (1998)
	CE	Gow, N.A., "Germ Tube Growth of <i>Candida albicans</i> ," <i>Curr. Topics Med. Myco.</i> 8, 43-55 (1997).
	CF	Hart, D.A., et. al., " <i>Staphylococcus Aureus</i> Strains Differ in Their in Vitro Responsiveness to Human Urokinase: Evidence that Methicillin-Resistant Strains are Predominantly Nonresponsive to the Growth-Enhancing Effects of Urokinase," <i>Can. J. Microbiol.</i> 42: 1024-31 (1966).
	CG	"Harry's Cosmeticsology", <i>Chemical Publishing</i> , 7 th ed. (1982)
	CH	Hiltz, M. E., et. al., "Anti-inflammatory Activity of a COOH-terminal Fragment of the Neuropeptide α -MSH," <i>FASEB J.</i> 3, 2282-2284 (1989).
	CI	Hiltz, M.E., "Anti-inflammatory Activity of α -MSH (11-13) Analogs: Influences of Alterations in Stereochemistry," <i>Peptides</i> 12, 767-71 (1991).

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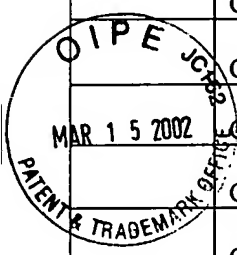
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CJ	Hiltz, M.E., et. al., "Alpha-MSH Peptides Inhibit Acute Inflammation and Contact Sensitivity," <i>Peptides</i> 11:979-982 (1990)
CK	Hiltz, M.E., et. al., "α-MSH Peptides Inhibit Acute Inflammation Induced in Mice by rIL-1β, rIL-6, rTNF-α and endogenous pyrogen but not that cause by LTB4, PAF and rIL-8," <i>Cytokine</i> 4(4):320-328 (1992)
CL	Holdeman, M., et. al., "Antipyretic Activity of a Potent α-MSH Analog," <i>Peptides</i> 6, 273-5 (1985).
CM	Huang, et al., Role of central melanocortins in endotoxin-induced anorexia, <i>Am. J. Physio (Regulatory, Integrative & Comparative Physiology, Vol. 276, No. 3, pgs R864-R871 (1999)</i>
CN	Huh S-K, Lipton JM and Batjer HH. The protective effects of α-melanocyte stimulating hormone on canine brainstem ischemia. <i>Neurosurgery</i> 40:132-139, 1997.
CO	Ichiyama T, Sakai T, Catania A, Barsh GS, Furukawa S, Lipton JM. Systemically administered α-melanocyte-stimulating hormone peptides inhibit NF-κB activation in experimental brain inflammation. <i>Brain Research</i> 836: 31-37, 1999.
CP	Ichiyama T, Zhao H, Catania A, Furukawa S, Lipton JM. α-melanocyte-stimulating hormone inhibits NF-κB activation and IαBκ degradation in human glioma cells and in experimental brain inflammation. <i>Experimental Neurology</i> 157:359-365, 1999.
CQ	Ichiyama T, Campbell IL, Furukawa S, Catania A, Lipton JM. Autocrine α-melanocyte-stimulating hormone inhibits NF-κB activation in human glioma cells. <i>Journal of Neuroscience Research</i> 58:684-689,1999.
CR	Ichiyama T, Okada K, Campbell IL, Furukawa S, Lipton JM. NF-κB activation is inhibited in human pulmonary epithelial cells transfected with α-melanocyte-stimulating hormone vector. <i>Peptides</i> 21: 1473-1477, 2000.
CS	Ichiyama T, Sakai T, Catania A, Barsh GS, Furukawa S, Lipton JM. Inhibition of peripheral NF-κB activation by central action of α-melanocyte-stimulating hormone. <i>Journal of Neuroimmunology</i> 99: 211-217, 1999.
CT	Lichtensteiger, W., and Monnet, F., "Differential Response of Dopamine Neurons to α-Melanotropin and Analogues in Relation to Their Endocrine and Behavioral Potency," <i>Life Sci.</i> 25:2079-2087 (1979)
CU	Lipton, J.M., et.al., "Anti-inflammatory Effects of the Neuropeptide α-MSH in Acute Chronic and Systemic inflammation," <i>Ann. N.Y. Acad. Sci.</i> 741, 137-148 (1994).
CV	Lipton, J.M., et. al., "Anti-inflammatory Actions of the Neuroimmunomodulator α-MSH," <i>Immunol. Today</i> 18, 140-145 (1997).
CW	Lipton, J.M., "Neuropeptide α-Melanocyte-Stimulating Hormone in Control of Fever, the Acute Phase Response, and Inflammation," <i>Neuroimmune Networks: Physiology and Diseases</i> , (Alan R. Liss, Inc. 1989) pp. 243-250
CX	Lipton, J.M., Modulation of Host Defense by the Neuropeptide α-MSH," <i>The Yale Journal of Biology and Medicine</i> 63: 173-182 (1990)
CY	Lipton JM, Catania A, Ichiyama T. Marshalling the anti-inflammatory influence of the neuroimmunomodulator α-MSH. <i>News Physiol. Sci.</i> 15: 192-195, 2000.
CZ	Lipton JM, Catania A. The neuropeptide α-MSH: a modulator of host reactions. <i>Seminars in Clinical Immunology</i> 10: 25-29, 1995.
DA	Lipton, et al., Mechanisms of antiinflammatory action of the neuro immunomodulatory peptide alpha-MSH, <i>Annals of the N.Y. Acad. Sci.</i> , vol. 840, pgs. 373-380 (1998)
DB	Luger, T.A., et. al., "Production of Immunosuppressing Melanotropins by Human Keratinocytes," <i>Ann. N.Y. Acad. Sci.</i> 680: 567-570 (1993)
DC	Lyson, K., et. al., "Binding of Anti-Inflammatory α-Melanocyte-Stimulating Hormone Peptides and Proinflammatory Cytokines to Receptors on Melanoma Cells," <i>Neuroimmunomodulation</i> , 1:121-126 (1994)
DD	Macaluso, A., et. al., "Antiinflammatory Influences of α-MSH molecules: Central Neurogenic and Peripheral Actions," <i>The Journal of Neuroscience</i> , 14(4): 2377-2382 (1994)
DE	Mayhall, Ten Home Remedies for Sunburn, <i>Seasonal Health</i> , (July 14, 2000), < http://drkoop.com/wellness/seasonal/summer/sunburn.html >.


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	DF	Mugridge, K.G., et. al., "α-Melanocyte-Stimulating Hormone reduces interleukin-1β effects on rat stomach preparations possibly through interference with type I receptor," <i>European Journal of Pharmacology</i> , 197: 151-155 (1991)
	DG	Noisakran S., e. al., "Lymphocytes Delay Kinetics of HSV-1 Reactivation from in vitro Explants of Latent Infected Trigeminal Ganglia," <i>J. Neuroimmunol.</i> 95(1-2):126-35 (1999)
	DH	Patel, A., et. al., "Herpes Simplex Type 1 Induction of Persistent NF-κB Nuclear Translocation Increases the Efficiency of Virus Replication," <i>Virology</i> 247(2):212-22 (1998)
	DI	Potts, Sunlight, Sunburn, and Sunscreens, <i>Postgrad. med.</i> , 87:52-61 (1990).
	DJ	Rajora, N., et.al., "α-MSH Modulates Local and Circulating tumor Necrosis Factor α in Experimental Brain Inflammation," <i>J. Neurosci.</i> 17, 2181-2186 (1997).
	DK	Rajora, N., et. al., "α-MSH Production Receptors and Influence on Neopterin, in a Human Monocyte/macrophage Cell Line," <i>J. Leukoc. Biol.</i> 59, 248-253 (1996).
	DL	Rajora N, Boccoli G, Catania A and Lipton JM. α-MSH modulates experimental inflammatory bowel disease. <i>Peptides</i> 18:381-385, 1997.
	DM	Remington's Pharmaceutical Sciences, <i>Mack Publishing Co.</i> , 18 th ed. (1990)
	DN	Richards, D.B., et. al., "Effect of α-MSH (11-13) (lysine-proline-valine) on Fever in the Rabbit," <i>Peptides</i> 5, 815-817 (1984).
	DO	<i>Robbins Pathologic Basis of Disease</i> 5 th ed., Saunders Co., Philadelphia (1994) p. 335-337, 354-355, 1008, 1037-1038.
	DP	Ryan, et al., "Inflammation," a <i>Scope Publication</i> , The Upjohn Company, (1977)
	DQ	Star, R.A., et. al., "Evidence of Autocrine Modulation of Macrophage Nitric Oxide Synthase by α-MSH," <i>Proc. Nat'l. Acad. Sci. (USA)</i> 92, 8015-8020 (1995).
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	EB	Wong, K.Y., et. al., "A Potential Mechanism of Local Anti-inflammatory Action of Alpha-Melanocyte-Stimulating Hormone within the Brain: Modulation of Tumor Necrosis Factor-Alpha Production by Human Astrocytic Cells," <i>Neuroimmunomodulation</i> , 4:37-41 (1997)
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